Decision Memo for Transplant Centers: Re-Evaluation of Criteria for Medicare Approval (CAG-00061N)

Decision Summary

We will be issuing a revised Medicare national coverage decision in the Coverage Issues Manual. The revised instructions will maintain the existing standards for patient selection, patient management, commitment, facility plans, survival rates, maintenance of data, organ procurement, laboratory services, and billing. The volume criterion will be altered to require 12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung transplants. We will eliminate the 2-year minimum experience requirement.

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Decision Memo

To: File: Re-evaluation of Criteria for Medicare Approval of Transplant Centers CAG–00061N

From:

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Re: National Coverage Policy Request

Date: July 26, 2000

This memorandum serves four purposes: (1) outlines current coverage policy for organ transplantation; (2) describes the problem generating concern; (3) analyzes relevant clinical literature; and (4) delineates Medicare's response to this request for a national coverage policy.

Present Medicare Policy For Coverage of Heart, Liver and Lung Transplantation

Over the past 13 years we have published several notices in the **Federal Register** delineating Medicare's policy regarding various organ transplants. On April 6, 1987, we published a notice of HCFA ruling (52 FR 10935) (HCFAR 87-1) announcing Medicare's national coverage policy on heart transplants. On April 12, 1991, we published a final notice (56 FR 15006) that announced Medicare's national coverage policy on liver transplants in adults. On February 2, 1995, we published a notice with comment (60 FR 6537) outlining our policy regarding Medicare coverage of lung transplants.

In these notices, we stated that organ transplants in adults were medically reasonable and necessary when performed on carefully selected patients in facilities that meet certain criteria. As discussed in these notices, we based these policies on research carried out by the Battelle Human Affairs Research Center (heart) and the Public Health Service's Center for Health Care Technology (liver and lung). The specified facility criteria for all three organ types include the following:

- Patient selection - A facility must have adequate written patient selection criteria and an implementation plan.
- Patient management - A facility must have adequate patient management plans and protocols that include therapeutic and evaluative procedures for the waiting period, in-hospital period, and post-transplant phases of treatment.
- Commitment - The facility must make a sufficient commitment of resources and planning to the transplant program to demonstrate the importance of the program at all levels. Indications of this commitment must be broadly evident throughout the facility. The facility must use a multidisciplinary team that includes representatives with expertise in the appropriate organ specialty (i.e., hepatology, cardiology, or pulmonology) and the following general areas: vascular surgery, anesthesiology, immunology, infectious diseases, pathology, radiology, nursing, blood banking, and social services.
- Facility plans - The facility must have overall facility plans, commitment, and resources for a program that ensures a reasonable concentration of experience.
- Experience and survival rates - The facility must demonstrate experience and success with clinical organ transplants. The facility staff must have performed a specified volume of transplants for each organ type (12 or more adult heart or liver transplants or 10 or more lung transplants) for covered conditions in each of the two preceding 12-month periods. Additionally, the facility must demonstrate a minimum actuarial 1-year and 2-year survival rate. Heart transplant hospitals must demonstrate actuarial survival rates of 73 percent for 1 year and 65 percent for 2 years. Liver facilities must demonstrate a 1-year actuarial survival rate of 77 percent and a 2-year actuarial survival rate of 60 percent for adult patients. Lung transplant facilities must demonstrate a 1-year actuarial survival rate of 69 percent and a 2-year actuarial survival rate of 62 percent.
- Maintenance of data - The facility must agree to maintain and, when requested, periodically submit data to us.
- Organ procurement - The facility must be a member of the Organ Procurement and Transplantation Network (OPTN) as an appropriate organ transplant facility and abide by its approved rules. The facility must also have an agreement with an Organ Procurement Organization (OPO).
- Laboratory services - The facility must make available, either directly or under arrangements, laboratory services to meet the needs of patients.

- Billing - The facility must agree to submit claims to Medicare only for transplants performed on individuals who have Medicare-covered conditions.

The policies state that a facility must be performing transplantation for a minimum of 2 years prior to applying for Medicare approval. While we will consider waiver of most requirements for facilities that demonstrate that they meet the program's long term goal of ensuring high quality care, this 2-year minimum experience is not waivable under any circumstance.

Description of the Problem

Medicare grants approval for transplantation at the facility level. This is based on the concept that quality of care and outcomes are a function of many elements of the facility and transplant team, and not solely determined by the individuals performing the procedure. Hospitals are responsible for developing policies and protocols for services furnished within its facility and for enforcing those policies among the staff working in the facility. We believe that successful organ transplantation requires the skills and experience of an interdisciplinary team. The facility provides a mechanism to develop that team, provide protocols to shape their NCDs, and a review mechanism to deal with problems that arise. We have not, therefore, approved individual transplant physicians, surgeons, or teams apart from the facility that is ultimately responsible for the care of the patients.

It is has become common practice for transplant surgeons and physicians to change the facilities in which they practice. For example since 1990, facilities have reported to the Organ Procurement and Transplantation Network approximately 175 transplant physicians or surgeons leaving their transplant program. Frequently, physician transfers are from one approved program to another approved program so that Medicare coverage of the physician's services is not affected.

More recently, entire transplant teams have moved from one hospital with a successful transplant program to open a new transplant program in another facility. These moving teams believe it is unfair to remove their ability to receive Medicare coverage for their transplant services based on their decision to change their place of employment.

In response to the concerns raised by the hospitals employing transplant teams transferring from experienced hospitals, we solicited scientific evidence from the community through our Internet site. Specifically, the questions we raised included the following:

1. Is there scientific evidence or data that support that safety, effectiveness, and medical appropriateness can be determined through evaluation of the experience of the transplant team rather than through evaluation of the facility?

2. Are there any members of the transplant team (transplant physician, transplant surgeon, immunologist, infectious disease specialist, pulmonologist, pathologist, radiologist, nursing, social services, blood banking) who could be replaced by any currently employed license holder in that discipline without affecting significantly the result of the transplant procedure? What evidence is there to support this conclusion?

3. When a transplant team transfers facilities, what assurances are there that the team retains the patient selection and patient management protocols that contributed to the outcomes achieved in the previous facility? What evidence is there to support this conclusion?

4. What evidence is there that a facility that has lost a transplant team will achieve the same or similar outcomes with a replacement team?

Summary of Relevant Clinical Literature

One commenter submitted information in response to our solicitation. The information consisted of: 1) pages from the Internet home page of a hospital stating the early outcomes of the new transplant program; 2) a list of hospitals that had a transplant physician leave; 3) the Bylaws of the Organ Procurement and Transplantation Network outlining the requirements for transplant surgeons and physicians; and, 4) a letter from a transplant applicant responding to concerns raised by HCFA's review of its application as a transplant center.

In addition, our staff conducted a literature search in an effort to locate scientific literature that might assist with this issue. We were not able to locate any literature that directly assessed the issue of the contribution of team competency or outcomes. We did, however, locate two articles related to the effect of transplant center volume on transplant outcomes. A 1994 Journal of American Medical Association article by Hosenpud et al. deals with heart transplantation and a 1999 article in the New England Journal of Medicine by Edwards et al discusses the effect of volume on liver transplantation. We reasoned that volume could possibly serve as a proxy for the 2-year minimum experience requirement in addressing the issue of whether a new transplant center staffed with an experience team might be expected to produce satisfactory outcomes.

The heart study used the Scientific Registry data of all cardiac transplant procedures in the United States from October 1987 through December 1991. Using modeled survival rates, the risk of mortality decreased to a basal level in those centers performing between eight and 10 transplant operations per year. In centers performing fewer than nine transplantations, mortality increased sharply and exponentially. Dividing centers into those that performed nine or more transplantations per years and fewer than nine transplantations per year, the increased risk of mortality at 1 month and 12 months was 40.3% and 33.1% respectively, in centers performing fewer than nine cardiac transplantation per year ($p<0.001$). These data demonstrate that the risk of mortality at early and intermediate time points is substantially higher in low-volume cardiac transplant centers.

The study performed a subgroup analysis on new centers to determine whether differences in low-volume centers were a function of the low volume directly or a function of overall experience. To do the subgroup analysis, the study analyzed outcomes in 13 centers whose initial year of operation was 1988. Comparing the outcome in the initial year with those in the subsequent year, the study determined that outcomes were worse in the subsequent year. This suggests that experience assessed as time in operation does not substitute for volume.

The Edwards, et al. study similarly analyzed all liver transplantation performed in the United States between October 1, 1987 and April 30, 1994. Because the results for the earlier period were largely similar to those from 1992 to 1994, they focused on the more recent period. The study methodology divided all liver transplantation centers as either high or low volume based upon whether they performed 20 or fewer transplants per year. The 1-year mortality rate for the low volume centers was 25.9 percent, as compared with 20.0 percent for the high volume centers. Low-volume centers that were affiliated with high-volume centers, such as pediatric transplantation programs, had results similar to those of the high-volume centers. The 1-year mortality rate at unaffiliated low-volume centers was 28.3 percent, as compared with a rate of 20.1 percent for the group of all high-volume centers plus affiliated low-volume centers ($p<0.001$). The study concluded that as a group, liver-transplantation centers in the United States that perform 20 or fewer transplantations per year have mortality rates that are significantly higher than those at centers that perform more than 20 transplantations per year.

Medicare's Response to the Request

After much searching of the literature and actively soliciting information from the public, we did not find any information that supported the concept of approval of the transplant team rather than the transplant facility. Thus, we continue to believe that the HCFA response to a similar proposal that was included in the April 12, 1991 Federal Register is appropriate. In that response we stated our belief that each transplant facility must be willing and able to provide the many resources that are required to assure a successful transplant program.

A facility must provide not only the transplant team itself, but must provide administrative and operational resources that direct and support the team. We believe it is appropriate to measure a number of factors beyond the qualifications of the transplant team to determine the facility's overall commitment to a successful transplant program. For example, patient selection policies, patient management protocols, and the facility's commitment to operational practices, such as quality improvement, all are significant contributors to the success of a transplant program. We do not believe that the experience of an individual or group of individuals is a satisfactory substitute for that institutional commitment. Nor have we found any scientific evidence that supports this position. We continue to believe that the acquisition of an experienced team by another facility should not permit that other facility to claim the first facility's hard-won success.

However, consideration of the literature referenced above has caused to us reconsider our present policy of requiring 2-years minimum experience prior to approval of a transplant center. It appears from the literature, that volume is a more accurate predictor of successful outcomes than minimum experience. As pointed out in the Hosenpud article, experience assessed as time in operation in heart transplant centers does not substitute for volume in being a predictor of outcomes. That is, the outcomes in 13 new low volume centers did not improved with more experience in their subsequent year of operation. While this specific issue was not studied for liver and lung transplant facilities, we have no reason to believe that the findings would be different, especially in light of the similar volume findings in the Edwards study. Consequently, we have decided to remove the minimum experience criterion from the Medicare coverage of approved transplant centers.

In addition, it appears from the literature linking volume to outcomes that it may not be necessary to maintain a 2-year volume criterion. That is, we believe that centers may be considered for Medicare approval once they have met a minimum volume per year. We are in the process of developing a Notice of Proposed Rulemaking that would provide for periodic re-evaluation of transplant centers for Medicare approval. Thus, we believe that it is reasonable to approve centers initially once they have met the Medicare criteria if they have obtained the existing volume criteria on an annual basis. That is, we will consider evaluation of a transplant center's application if the center performs 12 heart or liver transplants per year or 10 lung transplants per year. We acknowledge that this abbreviated period of experience will make the actuarial survival number less precise. However, given that soon we plan on holding the centers to periodic re-evaluation, we no longer believe it is necessary to make centers wait for Medicare approval when there is scientific evidence to indicate that the likelihood of their success is high. If we find that we have approved centers that fail to meet the survival criteria in the future, we will remove approval.

We will be issuing a revised Medicare national coverage decision in the Coverage Issues Manual. The revised instructions will maintain the existing standards for patient selection, patient management, commitment, facility plans, survival rates, maintenance of data, organ procurement, laboratory services, and billing. The volume criterion will be altered to require 12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung transplants. We will eliminate the 2-year minimum experience requirement.

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